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The listing of claims presented below replaces all prior versions, and listings, of claims in the application.

Listing of the Claims

Claims 1-21 (cancelled).

22. (Withdrawn) A method of treating and/or preventing a bacterial infection disease comprising: administering to a subject in need thereof, a pharmaceutical composition comprising: a pharmaceutically effective amount of benzoquinolizine-2-carboxylic acid antimicrobial drug of the formula (I) according to claim 1; singly or in combination with a pharmaceutically effective amount(s) of a retinoid, an antibacterial, a steroid/non-steroid antiinflammatory agent, an antifungal agent or mixtures thereof.

23. (Withdrawn) The method of claim 22, wherein the benzoquinolizine-2-carboxylic acid antimicrobial drug is RS-(+)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidi-n-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid arginine salt and solvatomorphic or polymorphic forms thereof.

24. (Withdrawn) The method of claim 33, wherein the benzoquinolizine-2-carboxylic acid antimicrobial drug is S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-- yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid arginine salt and solvatomorphic or polymorphic forms thereof.

25. (Withdrawn) The method of claim 33, wherein the benzoquinolizine-2-carboxylic acid antimicrobial drug is S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1- yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid 0.2 hydrate.

26. (Withdrawn) The method of claim 33, wherein the benzoquinolizine-2-carboxylic acid antimicrobial drug is S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-- yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid.

27. (Withdrawn) The method of claim 33, wherein the benzoquinolizine-2-carboxylic acid antimicrobial drug comprises about 0.1-10% by weight of the composition.

28. (Withdrawn) The method of claim 33, whercin the benzoquinolizine-2-carboxylic acid antimicrobial drug comprises about 1% by weight of the composition.

29. (Withdrawn) The method of claim 33, wherein the benzoquinolizine-2-carboxylic acid antimicrobial drug comprises about 0.5% by weight of the composition.

30. (Withdrawn) The method of claim 33, wherein the retinoid comprises adapalene.

31. (Withdrawn) The method of claim 33, wherein said antibacterial is selected from the classes of aminoglycosides, cephalosporins, diaminopyridines, oxazolidinones, sulfonamides, tetracyclines or combinations of these classes.

32. (Withdrawn) The method of claim 33, wherein the steroid comprises clobetasol.

33. (Withdrawn) The method of claim 33, wherein said non-steroid antiinflammatory agent is selected from the group consisting essentially of ibuprofen, indomethacin, ketoprofen, flurbiprofen, celecoxib, valdecoxib, rofecoxib, varecoxib, parecoxib, meloxicam, nimesulide, etodolac, combinations and mixtures thereof.

34. (Withdrawn) The method of claim 33, wherein the antifungal agent comprises butenafine.

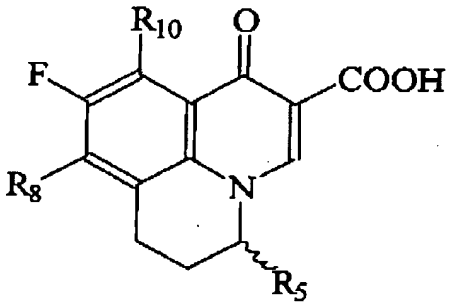
35. (Withdrawn) The method of claim 33, wherein said composition is in a physical form selected from concentrates, drops, pastes, ointments, creams, milks, pomades, powders, impregnated pads, tulles, solutions, gels, sprays, shampoos, lotions, suspensions, microspheres, nanospheres, lipidic vesicles, polymeric vesicles, polymeric patches or biological inserts.

36. (Withdrawn) The method of claim 33, wherein the subject is an animal or human.

37. (Withdrawn) The method of claim 33, wherein the route of administration is selected from ocular, nasal, otic, rectal, vaginal, intradermal, intratumoral, intralesional, intravascular, topical, transdermal, local, regional, or loco-regional.

38. (New) A stable pharmaceutical composition comprising:

a pharmaceutically effective amount of benzoquinolizine-2-carboxylic acid antimicrobial drug of the formula:

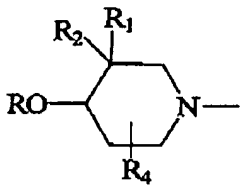


(I)

wherein:

R_5 is C_{1-6} alkyl, as a mixture of enantiomers or in a stereochemical orientation;

R_8 is



wherein R, R_1, R_2 and R_4 are hydrogen;

R_{10} is selected from H, C_{1-5} alkyl, amino, alkylamino and acylamino groups;

or an optical isomer, diastereomer or enantiomer thereof, or a polymorph thereof or pharmaceutically acceptable salt or hydrate thereof or mixtures thereof; in combination with a pharmaceutically effective amount(s) of a retinoid, or a steroid antiinflammatory agent, or a non-steroid, antiinflammatory agent or, or a non-steroid antiinflammatory agent, or an antifungal agent or mixtures thereof.

39. (New) The composition of claim 1, wherein the benzoquinolizine-2-carboxylic acid antimicrobial drug is selected from the group consisting of

RS-(±)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid;

R(+)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid;

S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid;

RS-(±)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid arginine salt and solvatomorphic or polymorphic forms thereof;

R(+)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid arginine salt and solvatomorphic or polymorphic forms thereof; and

S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo [i,j]quinolizine-2-carboxylic acid arginine salt and solvatomorphic or polymrphic forms thereof.

40. (New) The composition of claim 2, wherein the benzoquinolizine-2-carboxylic acid antimicrobial drug is S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid arginine salt and solvatomorphic or polymorphic forms thereof.

41. (New) The composition of claim 2, wherein the benzoquinolizine-2-carboxylic acid antimicrobial drug is S-(-)-9-fluoro-6,7-dihydro-8-(4-hydroxypiperidin-1-yl)-5-methyl-1-oxo-1H,5H-benzo[i,j]quinolizine-2-carboxylic acid.

42. (New) The composition of claim 1, wherein the benzoquinolizine-2-carboxylic acid antimicrobial drug comprises about 0.1 - 10 % by weight of the composition.

43. (New) The composition of claim 1, wherein the benzoquinolizine-2-carboxylic acid antimicrobial drug comprises about 1 % by weight of the composition.

44. (New) The composition of claim 1, wherein the benzoquinolizine-2-carboxylic acid antimicrobial drug comprises about 0.5 % by weight of the composition.

45. (New) The composition of claim 1, wherein said retinoid is selected from the group consisting of retinoic acid, adaplanene, isotretinoin, motretinide, tretinoin, tazarotene, combinations and mixtures thereof.

46. (New) The composition of claim 1, wherein the retinoid is adapalene.

47. (New) The composition of claim 1, wherein said steroid is selected from the group consisting of 21-acetoxypregnnolone, alclometasone, algestone, amcinonide,

beclomethasone, betamethasone, budesonide, chloroprednisone, ciclesonide, clobetasol, clobetasone, clocortolone, cloprednol, corticosterone, cortisone, cortivazol, deflazacort, desonide, desoximetasone, dexamethasone, diflorasone, diflucortolone, difluprednate, enoxolone, fluazacort, flucloronide, flumethasone, flunisolide, fluocinolone acetonide, fluocinonide, fluocortin butyl, fluocortolone, fluorometholone, fluperolone acetate, fluprednidene acetate, fluprednidene acetate, fluprednisolone, flurandrenolide, fluticasone propionate, formocortal, halcinonide, halobetasol propionate, halometasone, halopredone acetate, hydrocortamate, hydrocortisone, loteprednol etabonate, mazipredone, medrysone, meprednisone, methylprednisolone, mometasone furoate, paramethasone, prednicarbate, prednisolone, prednisolone 21-diethylaminoacetate, prednisolone sodium phosphate, predisone, prednival, prednylidene, pimexolone, tixocortol, triamcinolone, triamcinoloneacetonide, triamcinolone benetonide, triamcinolone hexacetonide, combinations and mixtures thereof.

48. (New) The composition of claim 1, wherein the steroid comprises clobetasol.

49. (New) The composition of claim 1, wherein the steroid comprises mometasone.

50. (New) The composition of claim 1, wherein said non-steroid antiinflammatory agent is selected from the group consisting of ibuprofen, indomethacin, ketoprofen, flurbiprofen, celecoxib, valdecoxib, rofecoxib, varecoxib, parecoxib, meloxicam, nimesulide, etodolac, combinations and mixtures thereof.

51. (New) The composition of claim 1, wherein said antifungal agent is a class selected from the group consisting of polyenes, allylamines, imidazoles, thiocarbamates, triazoles or combinations of these classes.

52. (New) The composition of claim 1, wherein said antifungal agent is selected from the group consisting of amphotericin, nystatin, caspofungin, griseofulvin, oligomycins, butenafine, naftifine, terbinafine, bifonazole, clotrimazole, ketoconazole, miconazole, liranaftate, tolnaftate, fluconazole, itraconazole, and voriconazole.

53. (New) The composition of claim 52, wherein the antifungal agent comprises butenafine.

54. (New) The composition of claim 1, wherein the pharmaceutically acceptable vehicle further comprises a pH modifying agent selected from acids, bases, inorganic basic salts, organic basic salts, buffering agents or mixtures thereof.

55. (New) The composition of claim 1, that is in a physical form and is selected from the group consisting of drops, pastes, ointments, creams, milks, pomades, powders, impregnated pads, tulles, solutions, gels, shampoos, lotions, suspensions, microspheres, nanospheres, lipidic vesicles, polymeric vesicles, polymeric patches and biological inserts.